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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: RONALD J. PETTIS, *et al.*

Confirmation No.: 4336

Application No.: 10/028,988

Group Art Unit: 3763

Filed: December 28, 2001

Examiner: Manuel A. Mendez

Attorney Docket No.: 11219-022-999
(500752-999021; P-4901P5)

For: METHODS AND DEVICES FOR
ADMINISTRATION OF
SUBSTANCES INTO THE
INTRADERMAL LAYER OF SKIN
FOR SYSTEMIC ABSORPTION

Date: February 2, 2005

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references **BS-DU** listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant."

This application is a continuation-in-part of U.S. application No. 09/893,746, filed June 29, 2001, which is a continuation in part of U.S. application No. 09/606,909, filed June 29, 2000. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed references **BS-DU** have not been included herein as such copies are available in parent application No. 09/606,909, filed June 29, 2000. Applicants will provide copies of references **BS-DU** upon request by the Examiner.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art"

against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

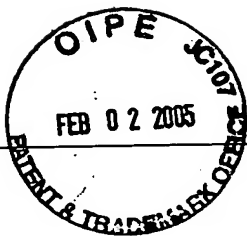
Applicants respectfully request that the references be made of record in the file history of the application.

No fee is believed due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones-Day-Deposit-Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Date: February 2, 2005

Respectfully submitted,

by *Jacqueline Benu* Reg No 43,492
Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)
JONES DAY
222 East 41st Street
New York, New York 10017



LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.
11219-022-999
(500752-999021,
P-4901P5)

APPLICATION NO.
10/028,988

APPLICANT
Ronald J. Pettis, et al.

FILING DATE
December 28, 2001

GROUP
3763

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BS	4,886,499	12/12/1989	Cirelli, et al.			
	BT	5,279,552	01/18/1994	Magnet			
	BU	5,582,591	12/10/1996	Cheikh			
	BV	5,848,990	12/15/1998	Cirelli, et al.			
	BW	6,056,716	05/02/2000	D'Antonio, et al.			
	BX	6,319,224	11/20/2001	Stout, et al.			
	BY	US 2003/0073609	04/17/2003	Pinkerton			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BZ	WO 94/23777	10/27/1994	PCT				
	CA	EP 0 429 842	08/28/1996	EP				
	CB	WO 97/21457	06/19/1997	PCT				
	CC	WO 00/09186	02/24/2000	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

CD	Agrawal et al., "Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in Mice," <i>Proc. Natl. Acad. Sci. USA</i> 88:7595-7599 (1991)
CE	Autret et al., "Comparison of pharmacokinetics and tolerance of calcitonine administered by intradermal or subcutaneous route," <i>Fundamental Clinical Pharmacology</i> 3(2):170-171 (1989)
CF	Bader, "Influenza vaccine experience in Seattle," <i>Am. J. Public Health</i> 70(5):545 (1980)
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CJ	Bronaugh et al., "Methods for in vitro percutaneous absorption studies. II. animal models for human skin," <i>Toxicol Appl. Pharmacol.</i> 62(3):481-488 (1982)
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CQ	Crooke et al., "A pharmacokinetic evaluation of c-labeled afovirsen sodium in patients with genital warts," <i>Clinical Pharmacology & Therapeutics</i> 56(6):641-646 December (1994)
CR	Crowe, "Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine," <i>Am. J. Med. Technol.</i> 31(6):387-96 (1965)
CS	Firooz, et al., "Benefits and risks of intralesional corticosteroid injection in the treatment of dermatological diseases," <i>Clinical and Experimental Dermatology</i> 20(5):363-370 (1995)
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CV	Goodarzi et al., "Organ distribution and stability of phosphorothioated oligodeoxyribonucleotides in mice," <i>Biopharmaceutics & Drug Disposition</i> 13(3):221-227 (1992)
CW	Gramzinski et al. "Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration," <i>Mol. Med.</i> 4(2):109-18 (1998)
CX	Halperin et al., "A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature," <i>Am. J. Public Health.</i> 69(12):1247-1251 (1979)
CY	Haynes et al., "Ultra-long-duration local anesthesia produced by injection of lecithin-coated methoxyflurane microdroplets," <i>Anesthesiology</i> 63(5):490-499 (1985)
CZ	Herbert et al., "Comparison of responses to influenza A/New Jersey/76-A/Victoria/75 virus vaccine administered intradermally or subcutaneously to adults with chronic respiratory disease," <i>J. Infect. Dis.</i> 140(2):234-238 (1979)
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DF	McElroy et al., "Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine," <i>N. Engl. J. Med.</i> 281(19):1076 (1969)
DG	McGugan et al., "Adrenal suppression from intradermal triamcinolone," <i>The Journal of Investigative Dermatology</i> 40:271-272 (1963)
DH	Merriam-Webster's Collegiate Dictionary, 10 th Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306
DI	Niculescu et al., "Efficacy of an adsorbed trivalent split influenza vaccine administered by intradermal route," <i>Arch. Roum. Path. Exp. Microbiol.</i> 40(1):67-70 (1981)
DJ	Payler "Intradermal influenza vaccine using Portojet 1976," <i>Br. Med. J.</i> 2(6095):1152 (1977)
DK	Payler et al. "Intradermal influenza vaccination," <i>Br. Med. J.</i> 2(921):727 (1974)
DL	Scott et al., "Toxicity of Interferon," <i>British Medical Journal</i> 282:1345-1348 (1981)
DM	Supersaxo et al., "Recombinant human interferon Alpha-2a: delivery to lymphoid tissue by selected modes of application," <i>Pharmaceutical Research</i> 5(8):472-476 (1998)
DN	Sutherest, "Treatment of pruritus vulvae by multiple intradermal injections of alcohol. a double-blind study," <i>British Journal of Obstetrics and Gynecology</i> 86:371-373 (1979)
DO	Sveinsson, "Investigation on the influence of insulin and adrenalin in rabbits with alimentary fatty liver and muscles and on the content of fat and sugar in blood," 8:66-86 (1939)
DP	Tauraso et al., "Effect of dosage and route of inoculation upon antigenicity of inactivated influenza virus vaccine (Hong Kong strain) in man," <i>Bull. World Health Organ.</i> 41(3):507-16 (1969)
DQ	The American Heritage College Dictionary, 2000, 3 rd Edition; Houghton Mifflin Company, Boston, New York, p. 368
DR	The Merck Manual of Diagnosis and Therapy, 1999, 17 th Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2555-2571
DS	Ward et al., "Puritus vulvae: treatment by multiple intradermal alcohol injections," <i>British Journal of Dermatology</i> 93(2):201-204 (1975)



	DT	Wu et al., "Pharmacokinetics of methoxyflurane after its intra-dermal injection as lecithin-coated microdroplets," <i>Journal of Controlled Release</i> 9:1-12 (1989)
	DU	Zaynoun et al., "The effect of intracutaneous glucocorticoids on plasma cortisol levels," <i>British Journal of Dermatology</i> 88(2):151-156 (1973)
EXAMINER		
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>		